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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,081	11/13/2003	David H. Coy	00537-164003	7933
37903	7590	01/08/2009	EXAMINER	
DAWN JANELLE AT BIOMEASURE INC. 27 MAPLE STREET MILFORD, MA 01757			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	
			MAIL DATE	DELIVERY MODE
			01/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,081	Applicant(s) COY ET AL.	
	Examiner MAURY AUDET	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-44 is/are pending in the application.
- 4a) Of the above claim(s) 32-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 18-31 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response are acknowledged.

The present application has been transferred from former Examiner Zhang to the present Examiner, where it had previously been transferred from former Examiner Muirhei. Both previous Examiners, as well as this Examiner have sent respective restriction requirements seeking an election of a single invention that may be searched without an undue burden, as the extremely broad peptide formula, bearing a known core. Examiner Muirhei had previously allowed the application, then withdrew the same based on the necessity for both 35 USC 102 and 103 rejections. Claims 32-43 are withdrawn as being drawn to non-elected subject matter.

Election/Restrictions

NOTE: Below under Objection, the amendment of the election by the Examiner to rejoin certain other peptides bearing the same substantial core structure as that originally elected.

Applicant's election of Group I, claims 18-31 and 44, as well the elected compound invention, H₂-B-Nal-D-Cys-Tyr-D-Trp-Lys-Val-Cys-(2R,3R-(2-hydroxymethyl)-3-hydroxy)propylamide, the latter with traverse of in the reply filed on 10/31/07 is acknowledged. The traversal is on the ground(s) that it would not pose an undue burden to search a known core, constituting less than a substantial core (e.g. under 4 contiguous amino acids). Applicant's arguments have been considered but are not found persuasive. The Examiner provided numerous options, as well as being open to other alternatives, both in writing and during an interview on 10/29/07, for Applicant to identify and elect a substantial core structure of this very well known compound for which a coextensive search thereof of many species emanating

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therefrom, could be conducted, without an undue search burden. This was never identified, or so claimed, by Applicant, and he instead elected the single compound noted above for prosecution on the merits. Due to the small somatostatin core being well known, and modified extensively within the art, a structure search of each species ends up turning on an individual, case-by-case compound search and analysis, due to the glut of art on these compounds. Hence, the necessity for a substantial, core structure (modified therein from the known native core) that emanates across multiple species, such that said species may be coextensively searched based on that core, without a undue search burden. A review of the myriad structures of such species is evident in e.g. claim 22, many bearing few overlapping residues, of which where evident generally fall within the known native residue of somatostatin. Absent the identification of such a core there between, each modified somatostatin antagonist is deemed a separate and distinct invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 18-31 and 44 are objected to because of the following informalities: the claims have not been amended commensurate in scope with the NEWLY elected invention (bearing core of originally elected H2-B-Nal-D-Cys-Tyr-D-Trp-Lys-Val-Cys-(2R,3R-(2-hydroxymethyl)-3-hydroxy)propylamide); namely a peptide selected from the group consisting of (see Interview Summary mailed 6/26/08):

the following 7 peptides 6 of which bear an overlapping core), to which the

Examiner agreed to rejoin:

H2-Phe-D-Cpa-Tyr-D-Trp-Lys-Val-Phe-Thr-NH₂

H2-beta-Nal-D-Cpa-Tyr-D-Trp-Lys-Val-Phe-Thre-NH₂

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H2-beta-NaI-D-Cpa-Tyr-D-Trp-Lys-Val-Phe-beta-NaI-N H2

H2-beta-NaI-D-Cpa-Tyr-D-Trp-Lys-Val-Phe-Thr-NH2

H2-D-beta-NaI-D-Cpa-Tyr-D-Trp-Lys-Val-Phe-Thr-NH2

H2-D-beta-NaI-D-Cpa-Tyr-D-Trp-Lys-Val-Phe-beta-NaI-N H2

&

H2-D-Phe-D-Phe-Tyr-D-Trp-Lys-Thr-Phe-Thr-NH2.

As the NEWLY elected invention was not found to be reasonably taught or suggested by the prior art of record, in the updated compound search conducted on 6/13/08, were the claims amended thereto, they would likely receive favorable consideration.

Applicant's own earlier works, now US 6,703,481 B1 and US 6,262,229 B1 are deemed the closest prior art of record, but neither is found to claim the elected compound above.

Appropriate correction is required.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 1/2/09

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654

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